VES-MATIC CUBE 30

OPERATING MANUAL

Software release 2.06

Automatic professional laboratory device for the determination of the erythrocyte sedimentation rate (ESR)

(patented)

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INNOVATIVE CLINICAL DIAGNOSTIC SYSTEMS

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Printed in 2010. [Total number of pages:67]

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CHAPTER 1

INTRODUCTION 1

Before installation and use of the instrument, **for safety reasons**, it is advisable to **read carefully** the warnings and instructions contained in this user manual.
It is important that this user manual is kept with the device for future reference.
In the case of sale or transfer, make sure that this manual accompanies the VES-MATIC Cube 30 to allow the new users to be informed about the instrument functionality and its related warnings.
Use of this instrument is recommended by **qualified and skilled personnel only**.

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1.1. PRESENTATION OF THE INSTRUMENT

The VES-MATIC cube 30 is a bench tool that can measure the erythrocyte sedimentation rate (ESR) of 30 blood samples (human and animal) at the same time.
The instrument carries out the ESR analysis directly from the test tubes being used on the blood cell counter in the laboratory; duplicate samples or extravasation of biological material are therefore unnecessary.
The test is carried out automatically and the results are comparable with the ones obtained using the Westergren method.
The instrument is managed by a microprocessor and its functionality will be described in more detail in the forthcoming paragraphs.

1.2. WARRANTY

DIESSE DIAGNOSTICA SENESE S.p.A. subjects all its products to strict quality controls. However, should the instrument show signs of malfunctioning despite these controls, you are invited to contact the authorised Technical Assistance Centre indicated to you at the time of delivery of the instrument.

General warranty regulations:

DIESSE DIAGNOSTICA SENESE S.p.A. guarantees the VES-MATIC Cube 30 for a period of 24 months from the delivery date (the date on the transport document shall be valid) for defects in the materials or manufacturing.
Should the product prove to be defective during the guarantee period the authorised Assistance Centres will repair it and you will only be charged the transport costs.

Terms:

1. The warranty is only acknowledged if the warranty certificate is sent within 30 days of the instrument being delivered, attaching a copy of the transport documents and the installation report.
2. The materials and manufacture of this product shall not be considered as defective if the instrument has been adapted, modified or adjusted to comply with national or local standards which differ from those for which the product has originally been designed and constructed.
   This warranty shall not cover said adaptations, modifications or adjustments or any attempts at the same, irrespective of whether performed correctly or incorrectly, or any damage deriving from the same.
3. This warranty shall not cover:
   - periodic checks, maintenance and repairs or replacement of parts due to normal wear and tear,

- transport costs and risks linked directly or indirectly to the warranty of this product, including the transfer from the assistance centre to the customer's address,
- damage due to neglect and improper use of the instrument,
- malfunctioning of the instrument due to modifications or repairs carried out thereon by unauthorised third parties.
- damage caused by the assembly of parts or components not approved by the manufacturer.

The WARRANTY CERTIFICATE is included among the APPENDIXES.

1.3. LIMITS OF RESPONSIBILITY

DIESSE DIAGNOSTICA SENESE S.p.a. assumes all liability for damages arising from manufacturing defects or malfunctioning of the instrument during the **foreseen use** of the same. It declines any other type of liability.
(Directive 1999/34/CE that amends the European Directive 85/374/EEC implemented in Italy via the Presidential Decree no. 224 dated 24 May 1988 (Legislative Decree no. 25 dated 02/02/2001).

1.4. REFERENCE LEGISLATION

The manufacturing company DIESSE DIAGNOSTICA SENESE S.p.a. declares that it abides by the manufacturing dispositions contained in the ISO 9000 standards.
It also declares that it has followed the Directives, shown below, for the design and manufacture of the VES-MATIC cube 30, as indicated in APPENDIX A (EC Declaration of Compliance):
98/37/EEC
89/336/EEC.

1.5. REQUEST FOR TECHNICAL ASSISTANCE

If Technical Assistance should be required, please contact the centre you were informed about when the instrument was delivered, otherwise contact Diesse Diagnostica Senese S.p.a.
See APPENDIX C.

1.6. REQUEST FOR SPARE PARTS

The request for spare parts indicated on the order form, see APPENDIX D, can be made by the customer (to request other spare parts, please refer to the Assistance Manual).

1.7. PRINTING AGREEMENTS

= READ THE OPERATIONAL MANUAL AND INSTRUCTIONS, OBSERVE THE SYMBOLS RELATING TO THE SAFETY FEATURES USED

= WARNING, DANGER OF PERSONAL INJURY, ALL THE CONDITIONS INDICATED IN THE TEXT MUST BE FULLY KNOWN AND UNDERSTOOD BEFORE PROCEEDING

= DANGER, POTENTIALLY INFECTED SUBSTANCE

= OBLIGATORY, CARRY OUT ALL FUNCTIONS DESCRIBED BELOW

= FORBIDDEN, DO NOT CARRY OUT THE FUNCTION DESCRIBED BELOW

= GENERAL INFORMATION

= PARTICULARLY IMPORTANT NOTES

= PRINTING THE DATA

= CLEANING THE INSTRUMENT BY THE OPERATOR

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INSTALLATION..... 5

This chapter aims to provide all the information required for identifying, installing and starting up the instrument.
Below is a list of the technical specifications and the product composition, as required by European Directives, to allow a safe use and disposal at the end of the life cycle.

The INSTALLATION must be carried out by an Technical Installer authorised by Diesse Diagnostica Senese SpA with a subsequent Installation Report. Refer to the Installation Check guide.

DISCONNECTION and **SHIPMENT** of the instrument must be performed by a Technician authorised by DIESSE Diagnostica Senese S.p.A.

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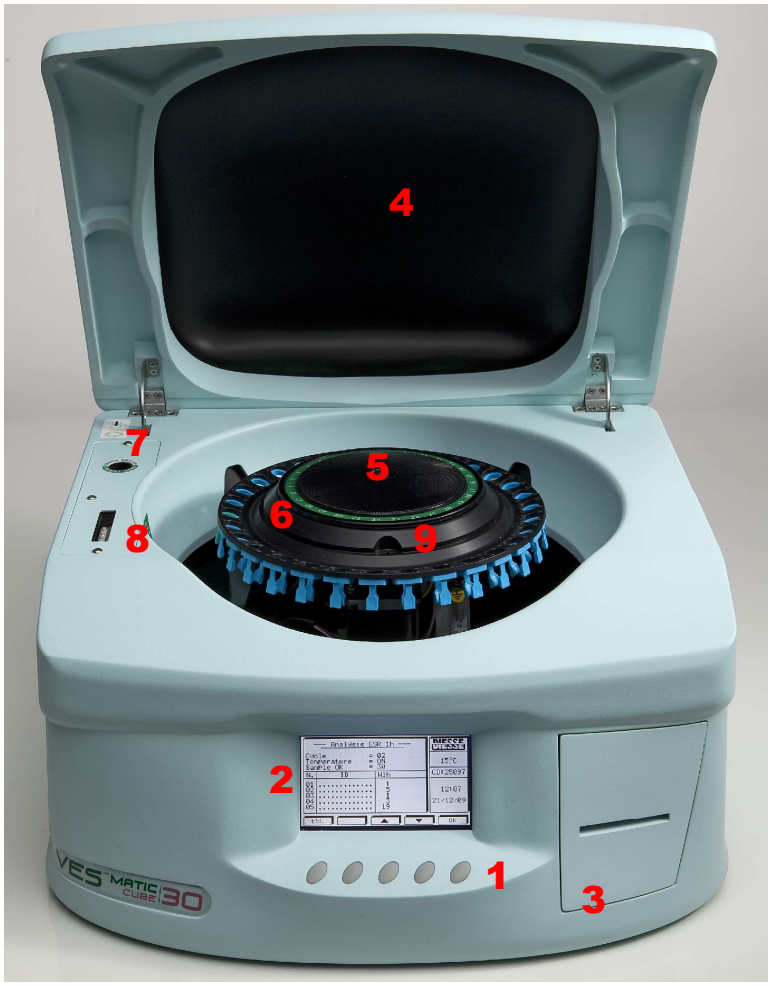
2.1. GENERAL DESIGN OF THE INSTRUMENT WITH EXTERNAL CONNECTIONS



LEGEND:

1) Keyboard
2) Display
3) Paper-holder drawer with printer hole
4) Sample-holder drawer door
5) 30-place Test-tube holder plate
6) Numbered test-tube holder positions
7) Housing for check device
8) Barcode reader
9) Housing for reducer plate required for rubbers

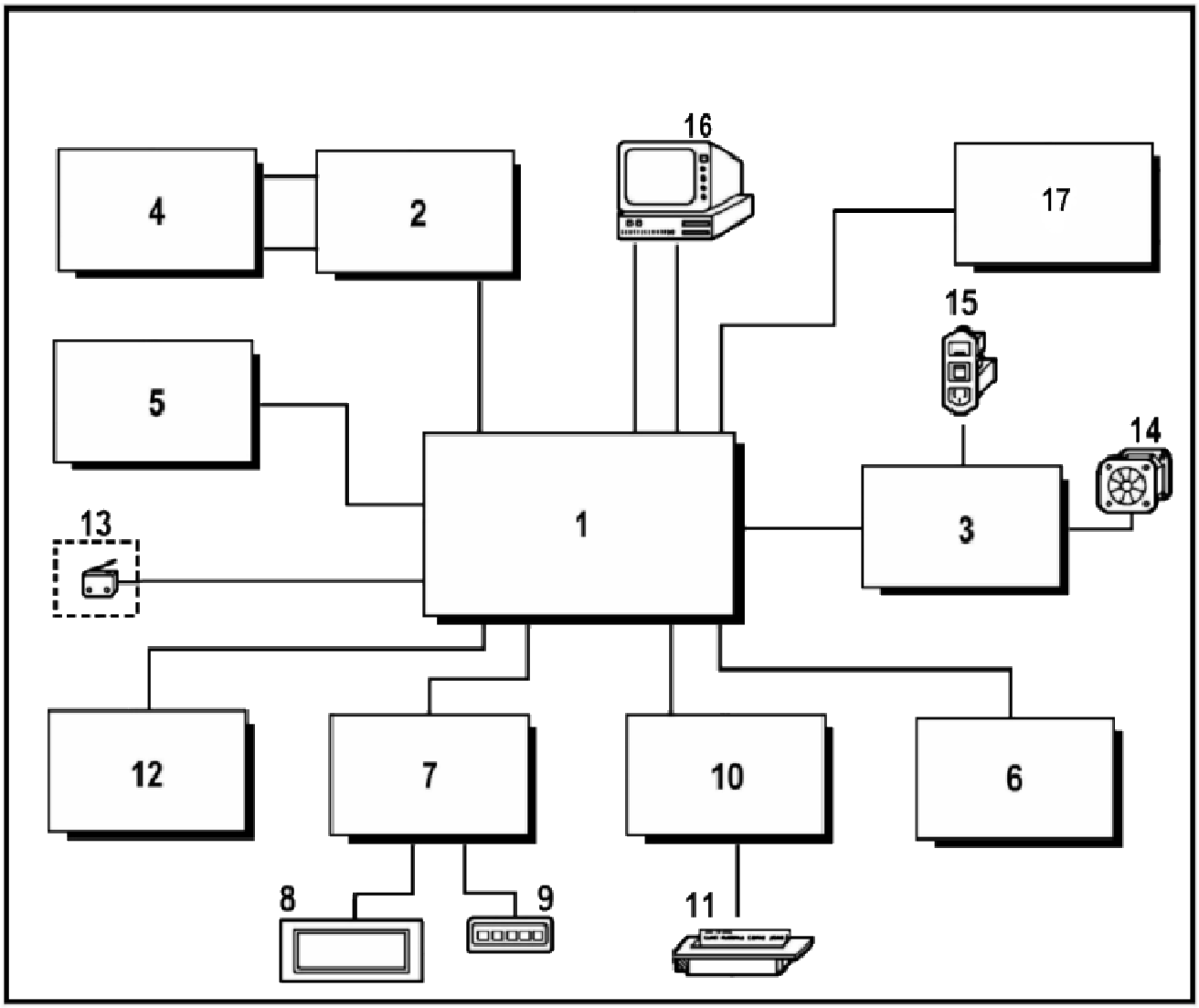
Fig 2.1.1 Front view

fig.2.1.2. 'Rear view'

LEGEND:

10) Switch (ON/OFF)
11) Fuses and voltage changer
12) Socket for power cable
13) RS-232 connector for connection to external computer
14) Connector 485
15) Forced-air fan

2.2. BLOCK DIAGRAM



The detailed diagrams can be found in the Assistance Manual

Fig. 2.2 "Block diagram – Ves-Matic Cube 30"

LEGEND:

1- CPU board
2- Motor Drivers board
3- Feeder
4- Motor block
5- Reading Sensor Unit
6- Check Device Unit
7- Display/Keyboard interface
8- Graphic display
9- Keyboard
10- Printer interfacer
11- Printer
12- Solenoid Unit door
13- Door Micro switch
14- Forced-air fan
15- ON/OFF switch with network filter
16- External connections
17- Barcode reader

2.3. TECHNICAL DESCRIPTION OF THE INSTRUMENT

CENTRAL UNIT

Controls and processes the incoming data from the sensors and manages all peripherals; it understands the FLASHEPROM which contains the programmes; it also contains the EEPROM where read and processed data is memorised.

OPTICAL READING UNIT

Unit made up of a photodiode – phototransistor pair.

MOTORS FOR TILTING AND ROTATION OF TEST-TUBE HOLDER PLATE

A motor tilts the test-tube holder plate to 90° and another motor turns it using the shaft, in order to ensure the homogeneous suspension of red blood cells.

OPTICAL READING MOTOR UNIT

Lifts the optical reading unit, for controlling the test tubes inside, the blood level and the sedimentation.

KEYBOARD

It has 5 buttons which are used to activate the various functions on the VES-MATIC cube 30.

TEST-TUBE HOLDER PLATE

The plate comprises a radial crown with 30 numbered sites for inserting the test tubes. These are symmetrically tilted compared to the rotation axis, to arrange the test tubes on the cone generator.

The test-tube holder plate also has a reducer, which is needed to use rubber test tubes.

Only use the plate reducer when rubber test tubes are used.

ACOUSTIC SIGNAL SYSTEM

This functions as an alert for the operator during specific phases of the work cycle:

A "beep" sounds each time the buttons on the keyboard are pressed.

TEMPERATURE SENSOR

It is used to measure the temperature and is placed on the central unit next to test-tube holder plates.

PRINTER

It prints the test results at the end of each work cycle.

DISPLAY

It is used to view all the instrument’s messages.

2.4. TECHNICAL SPECIFICATIONS

CENTRAL UNIT AND INTERFACES	With low-dissipation RISC 8 BIT technology; ATMEGA128 microprocessor
TEST-TUBE HOLDER	With 30 number places, it can hold various types of test-tubes.
OPTICAL UNIT	One couple of optic-electronic elements (Led & analogical sensor)
PRINTER	Alphanumeric with thermal paper 58 mm wide, 36 characters per line, speed 20 mm/sec.
DISPLAY	Liquid-crystal screen 240x128 pixel, back-lighting with cfl lamp.
POWER SUPPLY	110 to 230 VAC (50 - 60 Hz)
FUSES	2 x 1.0A Fast (5 x 20 mm)
ABSORBED ELECTRICAL POWER	65 W max
DIMENSIONS	510 x 350 x 500 mm (l x h x d)
WEIGHT	20 Kg
WORKING TEMPERATURE	from + 15°C to + 35°C
STORAGE TEMPERATURE	from + 5°C to + 45°C
RELATIVE HUMIDITY	from 20% to 80% without condensation
PLATE ROTATION SPEED	1 Rotation every 1.5 seconds during normal functioning.
CLASSIFICATION	CLASS 1 equipment (IEC classification)

2.5. SUPPLIED MATERIAL

The VES-MATIC Cube 30 is supplied with the following materials:
An INSTRUCTION MANUAL.
Two spare RAPID 1A fuses (5x20) each.
A plate reducer for using test-tubes.
An IEC International Standard power supply cable
[Female Plug IEC 320 C-13; Male Plug Schuko CEE 7-VII; Rating: 10A/250Vac].
- packing-list and installation report.
- Warranty certificate

Consumables that can be purchased for using the instrument

▪ Check device Transponder RF 1K for Ves-Matic Cube (1000 tests)	[Ref: 10292]
▪ Check device Transponder RF 5K for Ves-Matic Cube (5000 tests)	[Ref: 10291]
▪ Check device Transponder RF 10K for Ves-Matic Cube (10000 tests)	[Ref: 10290]
▪ ESR Control 9ml (2 Normal Bottles + 2 Abnormal Bottles)	[Ref: 10430
▪ ESR Control 9 ml (1 Normal Bottle + 1 Abnormal Bottle)	[Ref.: 10434]
▪ Thermal paper for printer (1 pack)	[Ref: 10403]

2.6. INSTRUCTIONS FOR TRANSPORT

The VES-MATIC cube 30 is a precision instrument and must be handled as such. Inappropriate operations may damage the internal opto-electronic parts and cause mechanical damage.
Given the machine's reduced volume and weight, it can be transported manually, using all necessary precautions, to avoid knocks and excessive tilting, which may damage the instrument.

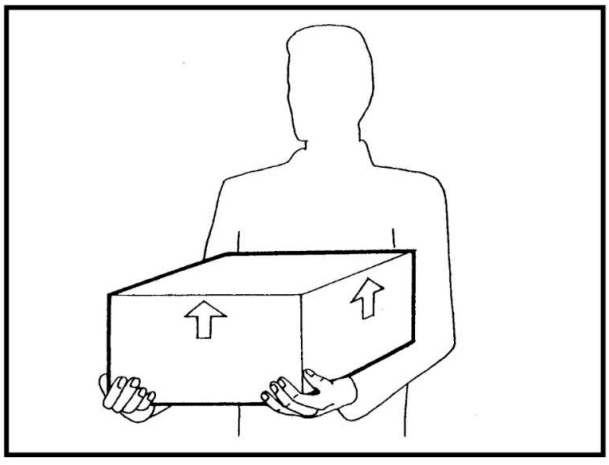


Fig.2.6

PACKAGING DIMENSIONS

WIDTH	Cm	61
HEIGHT	Cm	53
DEPTH	Cm	68
GROSS WEIGHT	Kg	26
PACKAGING WEIGHT	Kg	6

For any later transportation of the instrument, we recommend that the original packaging is preserved, including the internal parts (especially the polyurethane foam blocks that block the sample-holder plate in its housing).

2.7. PLACEMENT

The environment intended for this instrument is the laboratory.
For normal safety reasons and given the type of analysis carried out, the instrument must be placed away from sources of heat, in areas not accessible to liquids, in environments free from dust and on perfectly flat work benches that are not subject to shocks or vibrations.
The safety distances described, 20 cm back to wall, front of instrument free, left and right sides, 10 cm, must be observed to prevent the instrument from overheating (obstruction of fan) and to act quickly on the switch and power cable in the event of danger, to stop the machine from overheating. It is totally prohibited to place any material on the instrument for the same reason.

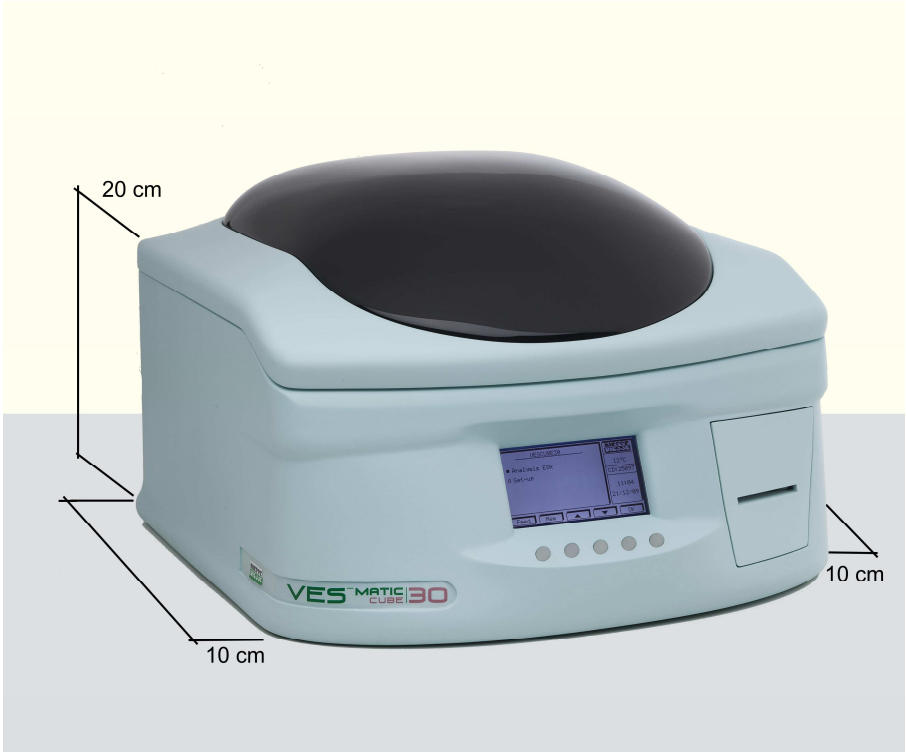


Fig. 2.7.

Never move the instrument after it is properly installed. Should movement or relocation of the instrument be necessary, a re-verification of the conditions listed in this paragraph would be required before using the instrument again. Whenever the instrument will not be used for an extended period of time it is suggested that it is disconnected from the power source and covered.

2.8. PREPARATION REQUIRED BY THE CUSTOMER

The instrument's and operator's safety is no longer guaranteed if one of the following conditions does not apply:

The power sourcework (installation *category II*) must be compatible with the electrical requirements, specifications and current indicated on the metal plate supplied on the rear of the instrument; it is advisable that the efficiency of the electrical system is periodically verified.

The network and relative outlets must be fitted with an efficient earthing connection following the laws in force.

The instrument has an internal power supply that stands variations in voltage as per specifications shown on the back plate of the equipment; if the line suffers from severe interference, use a normal saturated iron stabilizer (65 W minimum).

Before connecting with external instruments (host, PC Barcode Reader), it is necessary to verify compatibility (see the relative user manual) with the specifics indicated in chapter 7 and verify that the earth connection between them is uninterrupted.

The operator's protective equipment (gloves, containers for collecting used test-tubes, cleaning solutions for cleaning the instrument) must be available.

The operator must be trained to ensure awareness of the procedures, restrictions and warnings indicated in this manual in addition to the required laboratory safety procedures.

The location of the instrument should follow the guidelines indicated in paragraph above.

IT IS TOTALLY FORBIDDEN:

-To cover the back slits (fan) of the instrument

- remove or modify the safety and protection devices.

2.9. INSTALLATION PROCEDURE

1. To unpack the instrument
2. Control the supplied material
3. For positioning, please refer to paragraph 2.7.
4. Remove the polyurethane block that keeps the plate still.
5. Connect the cable to the power supply (satisfying point 2.8)
6. Turn on the instrument

Before using the instrument in the normal work cycle, a series of parameters concerning the test-tubes used in the laboratory must be set. This type of setting must be modified

SOLELY by an authorised Diagnostica Senese S.p.A. technician, as must be appear in the installation report supplied separately with the Installation Check Guide.

IN CASE OF FIRE OR GENERAL DANGER, TURN OFF THE INSTRUMENT AND UNPLUG THE POWER CABLE

2.10. COMPOSITION OF THE MACHINE, INDICATIONS FOR DISPOSAL

1 - The VES-MATIC cube 30 consists in percentages of:

IRON	20%
ALUMINIUM	20%
COPPER	8%
EPOXY RESINS and SILICON	6%
PLASTICS	45%

2 – **to dispose of the instrument** at the end of its life cycle, please refer to the local laws in force on waste disposal.

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3.1. THE INSTRUMENT

The VES-MATIC cube 30 is a bench instrument designed and planned to measure the Erythrocyte sedimentation rate (ESR) of up to a maximum number of 30 blood samples, contained in the same test-tubes coming from the blood cell counter used in the laboratory. In this way neither dual blood taking or a transfer of biological material are required.
The test is carried out automatically (shaking and reading) and the results are comparable with the ones obtained with the Westergren method (bibl. Reference 1-10), and if obtained at ambient temperature, can be taken to the temperature of 18℃ automatically using the Manley nomogram (fig. 3.1). The VES-MATIC cube 30 provides for excellent results equivalent to the Westergren method (1 hour) in just 33 minutes, including sample shaking.

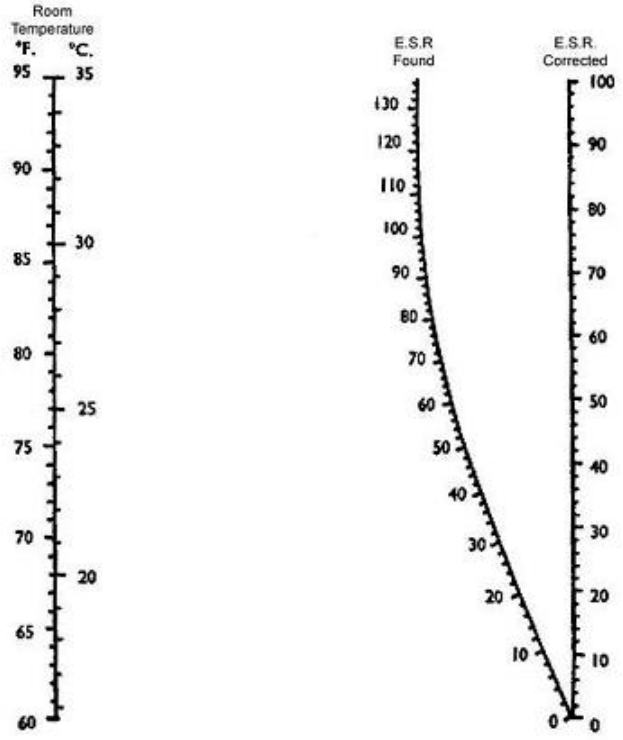

Fig.3.1

<u>Clinical concept of the ESR</u>

The instrument provides information about the erythrocyte sedimentation rate (ESR), a measurement of the acute response phase to an inflammatory pathology and that reflects the speed with which erythrocytes sediment. The ESR value measured in a certain moment is influenced by the concentration of some proteins whose plasma concentration changes in the presence of inflammation, and other pathologies (for example: neoplasms). It is also affected by some properties of the erythrocytes and the degree of anaemia (haematocrit).

Extremely high values are typical in multiple myeloma, leukaemia, lymphoma, breast and lung carcinomas, rheumatoid arthritis, SLE, pulmonary infarction. It is high in infections of any type, in carcinomas especially in the presence of liver metastasis, acute and chronic inflammations.

Normal ESR values (Westergren citrate)

During the first hour, ESR values are normally between 1 and 10 for men and between 1 and 15 for women; in pathological conditions results can increase to values of up to 100 and higher.

Normal range for the instrument VES-MATIC cube 30

MEN	up to 10 mm/hr
WOMEN	up to 15 mm/hr

Normal ESR values (Westergren EDTA)

In general, since the ESR value varies with age and gender, the reference values should respect this characteristic and should be established in relation to gender and age. The reference values should be established by the laboratory and in accordance with the "Guidelines for the determination of the reference values". Furthermore, there are other clinical variables (for example: the level of haemoglobin, some medicines, the menstrual cycle, pregnancy, smoking) that can influence ESR values and thus reflect also on the physiological reference values. To evaluate the values in EDTA consult the table present in the reference document: ICSH Recommendations for measurement of erythrocyte sedimentation rate. J. Clin. Pathol. 1993; 46: 198-203.

General functioning of the instrument:

The blood obtained in the CBC (cell blood count) test tube examination, is carefully mixed by the instrument; the samples then remain at rest for a predetermined amount of time, to allow sedimentation to occur.
Through the optic-electronic unit, the instrument automatically determines the sedimentation level of the erythrocytes; subsequently the information is extrapolated and then automatically printed or shown on the display (in the case of a host connection, please read paragraph 7)

3.2. WARNINGS

Potentially infected material is treated Abide by the EUROPEAN DIRECTIVES 89/391/EEC, 89/656/EEC, 89/654/EEC, 89/655/EEC, 90/269/EEC, 90/270/EEC, 90/394/EEC and 90/679/EEC
(Implemented in Italy in the Legislative Decree no. 626).

DISCONNECT the machine from the power source, before any technical intervention or in the case of malfunctioning of the instrument.

It is **forbidden to OPERATE** on the machine while any parts are moving.
(only commands can be typed on the keyboard).
It is forbidden to INTRODUCE fingers and objects between the instrument's plate and protective casing.

3.3. PERSONAL PROTECTION DEVICES

Observe personal and group safety measures foreseen for the operator and appropriate for the work environment. Refer to the local laws.

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4.1. KEYBOARD COMMANDS

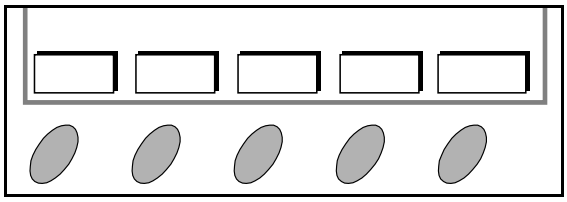


Fig. 4.1. "Keyboard"

The keys on the keyboard correspond to a virtual button at the bottom of the display. The buttons are reconfigured on the display each time a button is pressed, depending on the function selected.

The selected function is only activated when the corresponding key is pressed and released.

4.2. PREPARATION OF SAMPLES

No specific preparation of the test-tubes is necessary, as the Ves-Matic Cube 30 uses the ones from another analytic system (hemochromocytometric test). It is however necessary to follow the regulations used by the ICSH, the most important of which are stated below:

- The blood should be obtained by means of a withdrawal of the maximum duration of 30 seconds and without excessive venous stagnation.
- The blood can be gathered in both vacuum test tubes with EDTA as well as non-vacuum test tubes with EDTA. It is recalled that the Ves-Matic Cube 30 uses the test tubes directly from the blood cell counter.
- Mix the blood immediately after the withdrawal with at least 2 complete inversions of the test tube.

Compatible test-tubes are the ones described in figure 4.2.2.. In the event that a type of test-tube is used that has not been contemplated in the above examples, it is possible to request a compatibility check or a modification/reprogramming of the instrument by a specialised technician who has been authorised by DIESSE Diagnostica Senese SpA.

Fig. 4.2.1.

If rubber test-tubes are used, the reducer disk must be inserted on the plate.

The disk must only be used for rubber test-tubes (see paragraph 4.3.).

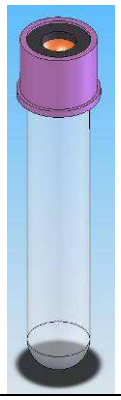
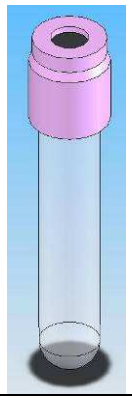
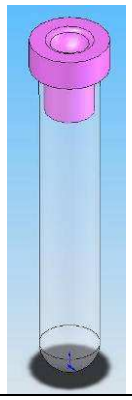
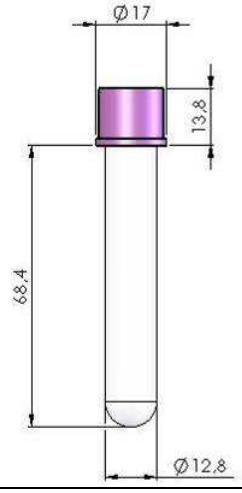
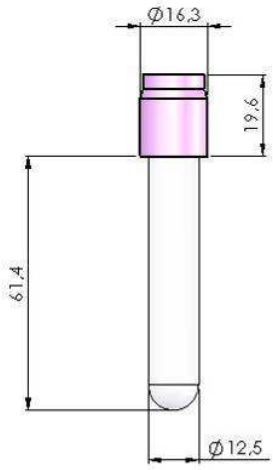
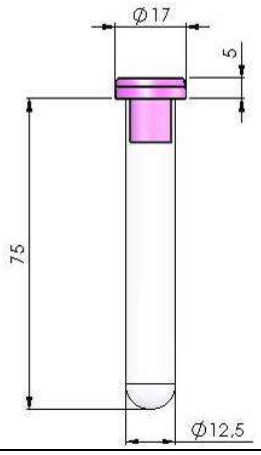
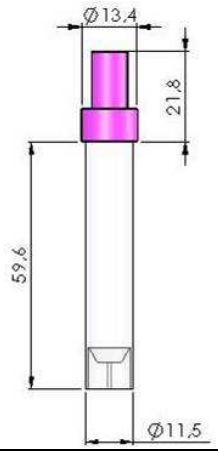
	VACUETTE (GREINER BIO-ONE)	VACUTAINER (BD)	RUBBER [RUBBER CAP] (BD, TERUMO)	SARSTEDT (SARSTEDT)
Model				
Dimensions (mm)				

Fig 4.2.2

Suitability of the sample

- the test is carried out within four hours of the blood being taken
- the test is conducted on a blood sample conserved at 4° for a maximum period of 24 hours. In this case, make sure that the sample has reached ambient temperature before inserting it into the instrument.
- Check that there is no coagulation, turning the test-tube upside down before inserting it into the instrument
- Verify that the test tube is **hermetically** closed

Sample Labelling

The Ves Matic Cube is prepared to work with maximum 2 labels that are not overlapping and which are applied to the test-tube sample to be analysed, reading it through a maximum of 3 paper layers, along the reading axis. Therefore if one test-tube has two labels, it is necessary to enter the sample in such a way that the reading axis has no more than three layers of paper (see figure).

It is also preferable to enter the samples in such a way that the sample layers are opposite the emitter.

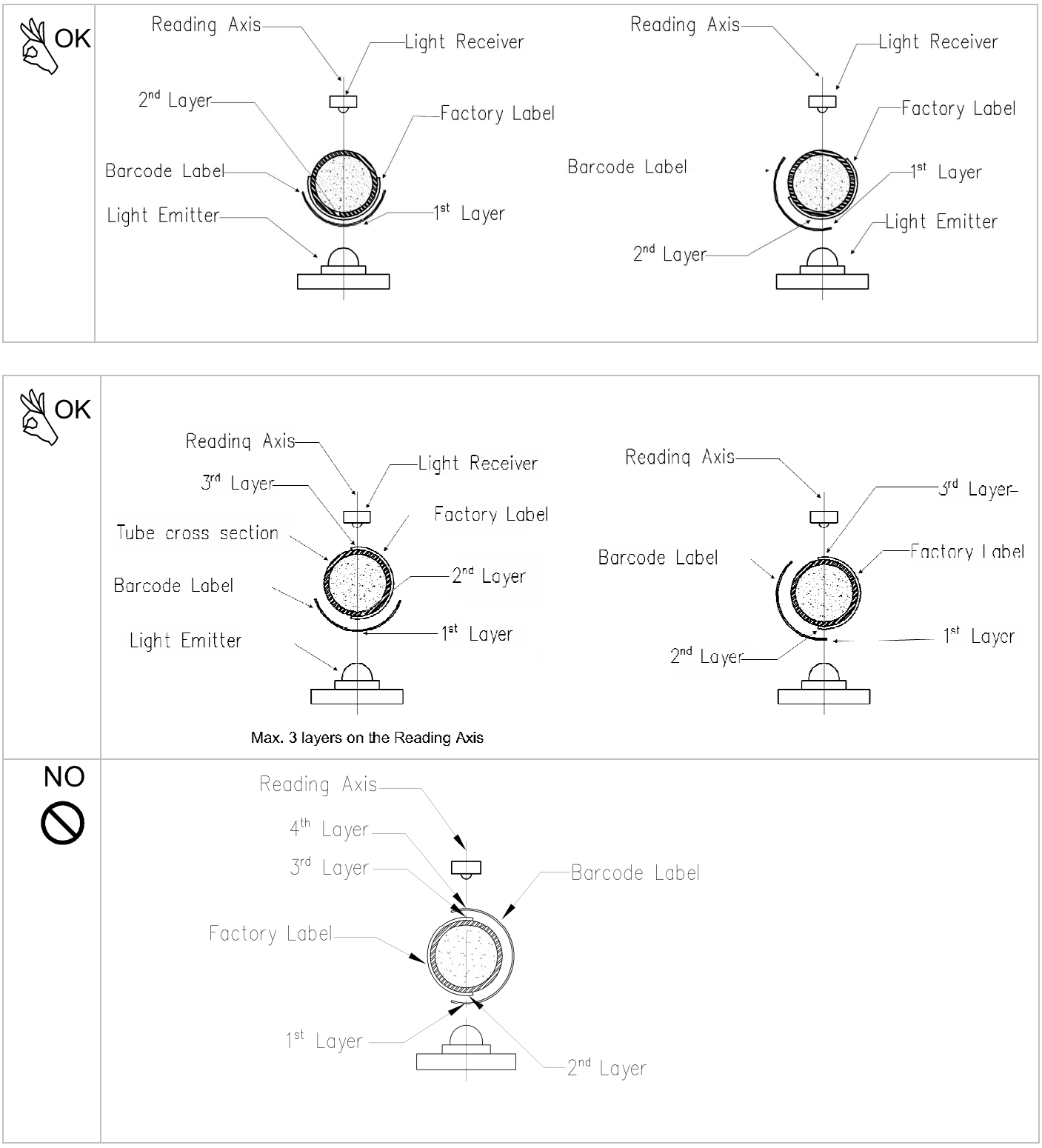

OK
Reading Axis
Light Receiver
2nd Layer
Factory Label
Barcode Label
Light Emitter
1st Layer
Reading Axis
Light Receiver
Factory Label
Barcode Label
1st Layer
Light Emitter
2nd Layer
OK
Reading Axis
3rd Layer
Light Receiver
Factory Label
Tube cross section
2nd Layer
Barcode Label
1st Layer
Light Emitter
Reading Axis
3rd Layer
Barcode Label
Factory Label
1st Layer
2nd Layer
Max. 3 layers on the Reading Axis
NO
Reading Axis
4th Layer
3rd Layer
Barcode Label
Factory Label
1st Layer
2nd Layer

Fig 4.2.3.

Filling of the test tube

The level of blood in the test-tube is fundamental for the correct carrying out of the ESR test by the Ves-Matic Cube 30. The instrument itself will verify the correct filling of the test tube, measuring the level and comparing it with the pre-set tolerance values of maximum and minimum level.

If overfilled (above 4 ml*) or underfilled (less than 1.5 ml*), the instrument prints a message. If the filling is excessive, it signals "HIGH", if the filling is insufficient it signals "LOW". In both cases the analysis must be repeated with the correct quantity of blood. The same message will appear on the results printout

**(the volume values above refer to the use of vacutainer test-tubes)*

4.3. TYPES OF TEST-TUBES

As already stated, the Ves-Matic Cube 30 can analyse different types of test-tubes (figure 4.2.2.), even during the same cycle, however there are limitations for rubber test-tubes, which require the reducer plate for processing.

Inserting the reducer plate

Assembling/dismantling the reducer above the plate is an extremely simple, an operation designed to be carried out several times in a working day in laboratories that need to process different types of test-tubes, including rubber ones.

- **Phase 1**

Place the reducer on the plate so that the 3 locking pins enter the housing (figure 4.3.1.) and they remain with the horizontal groove according to the plate numbers.

Fig 4.3.1

- **Phase 2**

Push the pin down and rotate by 90 degrees

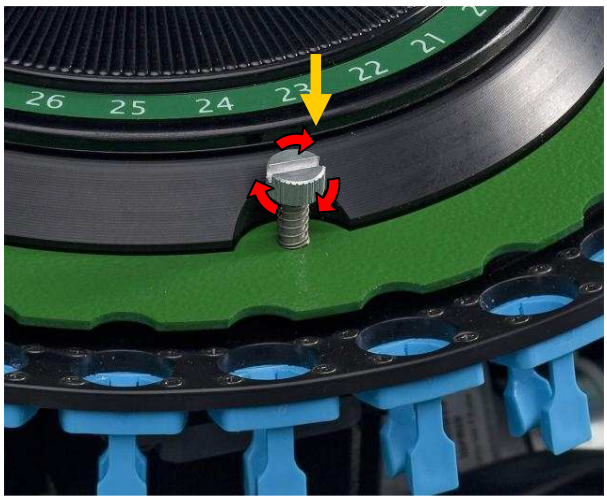


Fig 4.3.2.a

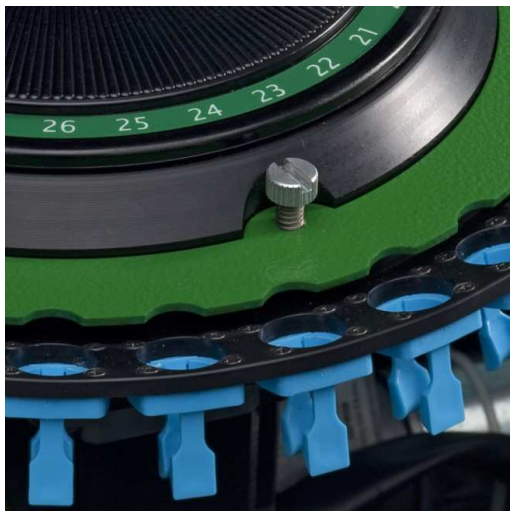


Fig 4.3.2.b

- **Phase 3**

Repeat the operation for the other pins too.

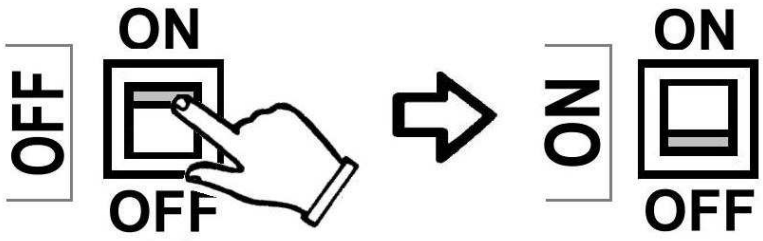
Remember that the reducer disk is assembled for the use of rubber test-tubes and that it must be removed to use vacutainer and vacuette test-tubes.

Sarstedt test-tubes are the only ones that can be inserted regardless of whether the reducer disk is in place or not.

4.4. SWITCHING ON THE INSTRUMENT

PROCEDURE:

After installing the instrument as shown in section 2, make sure the plate hatch is closed and then flip the switch on the back of the instrument to ON:

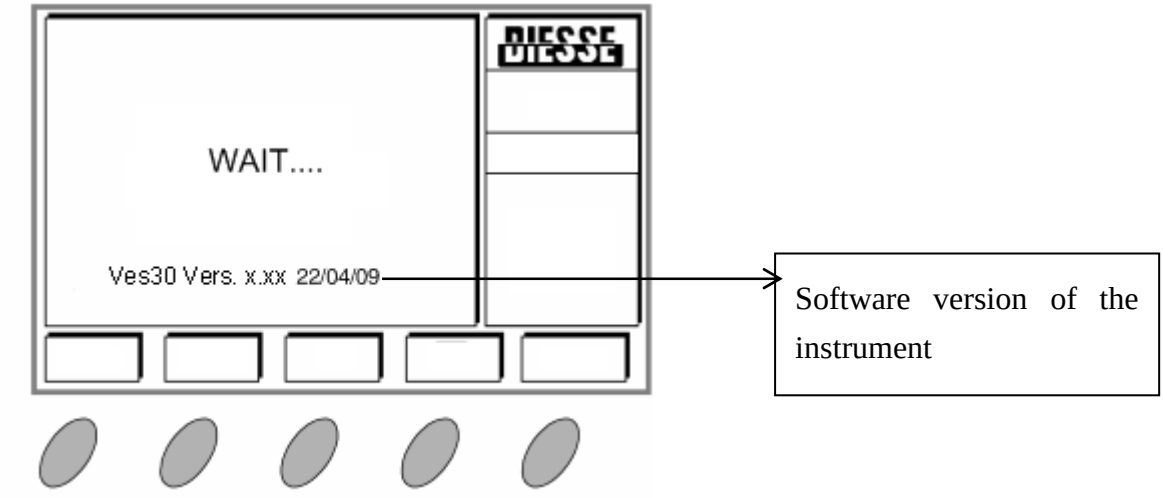


When turned on, the instrument carries out an initial Reset, checking the functions of all the internal units.

While the mechanical parts of moving, the hatch is blocked (closed) by a safety device. The hatch will only be released at the end of the cycle, at the end of movement or during the entry procedure used for the Identification Number with the barcode reader.

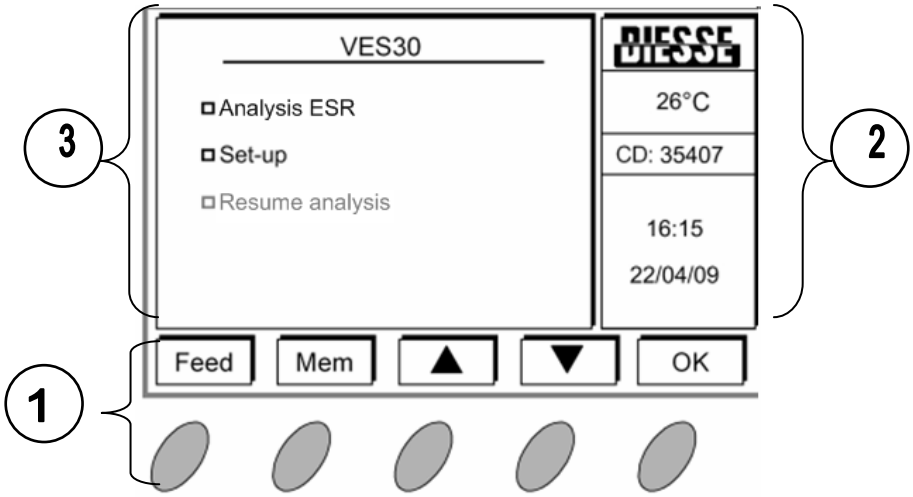
To open the hatch during the cycle, the cycle must be interrupted by means of the specific procedure (ESC key).

The following message appears on the screen during the preliminary controls:



4.5. MAIN MENU

The main menu appears on the screen when the preliminary controls have been completed:



The operations that can be carried out are contained in the main menu (3).

1 – Decription of **Keyboard**

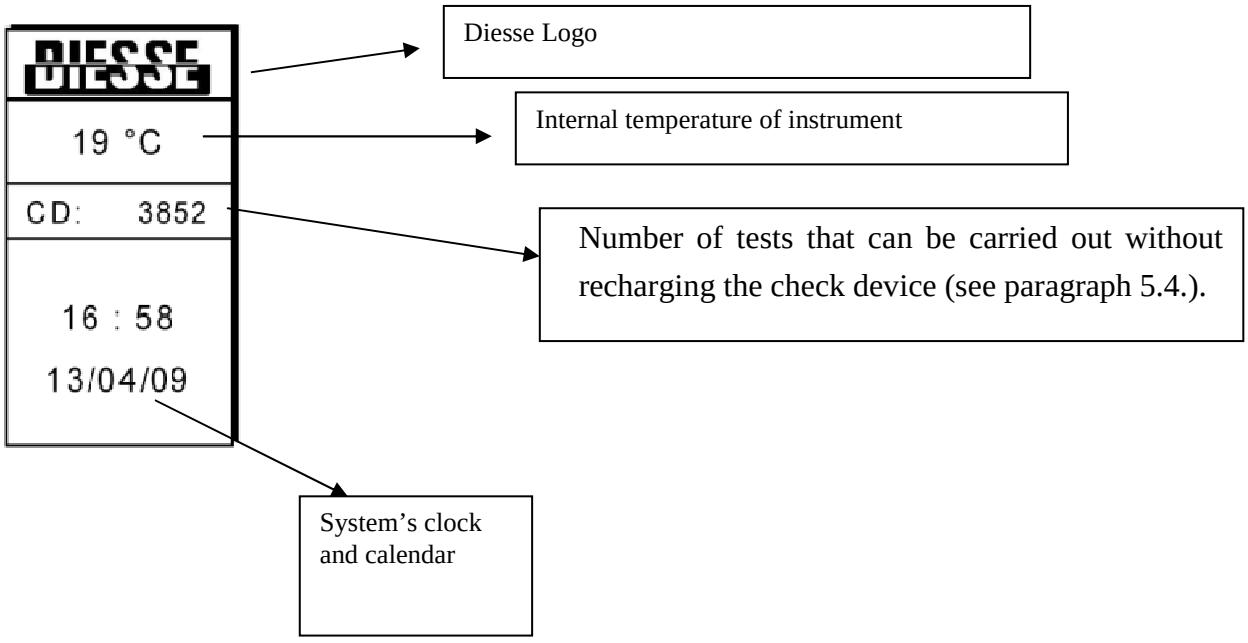
Feed – to feed paper into the printer.

Mem – to view the latest test cycles (in chronological order), if present; in the event of a new instrument or a recently updated instrument, with no stored results, the message “No analyses in the memory!!” will appear and then the main menu reappears after about 2 seconds.

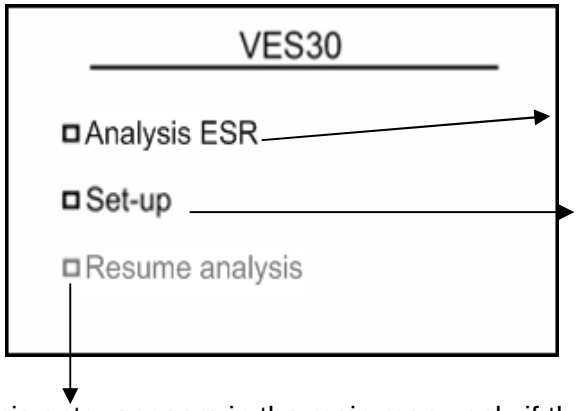
▲▼= arrow keys to scroll up and down the contents of the main menu (3)

OK - to confirm the item selected in the main menu (3)

2 Description


19 °C
CD: 3852
16 : 58
13/04/09
Diesse Logo
Internal temperature of instrument
Number of tests that can be carried out without recharging the check device (see paragraph 5.4.).
System’s clock and calendar

3 – Description of **Main Menu**



This entry appears in the main menu only if the last analysis cycle has been deliberately (A) or accidentally (B) interrupted.

E.g. to introduce new samples into free positions, to correct blood levels in samples, to correct entered data.

(B) E.g. to interrupt the power supply.

The programme creates a backup file containing the information on the tested test-tubes, such as the ID number, acquired using the barcode reader, and the samples introduced up to that moment.

4.6. DESCRIPTION OF ANALYSIS CYCLE

It also supplies results in agreement with the Westergren method using readings after one hour.

Total duration **of test – 33 minutes**.

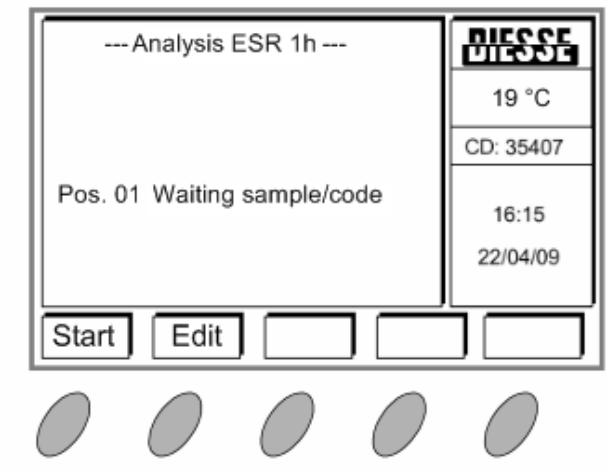
An analysis cycle can be broken down into five main operations:

- Loading
- Sample shaking
- Reference reading
- Sedimentation
- Analytical reading

A detailed description of the various analytical cycle phases is given below.

LOADING

Once the analysis cycle has started, the instrument rotates the plate and stops at the position number one and the instrument will show the following screen display.



It will then be possible to enter the sample code and then the test-tube, or the test-tube directly is the traceability given by the plate number is sufficient (in this case, it is better to set the working mode to OFF (see paragraph 4.9.5.).
To enter the code, the reader located inside the hatch can be used, or it can be entered manually on the keypad, pressing the edit key.
Once the code has been entered, a request to insert the sample appears on the screen (if connection to host applies, see paragraph below).
Before introducing the sample in the first free position, shake it twice so that the reading unit recognises the presence of the test-tube and moves the plate forward one position (regardless of whether the code has been entered or not).

Remember that the code can only be entered before placing the sample inside the instrument.

Following this procedure up to sample number 30, it will be possible to move onto the next phase, however if there are fewer than 30 samples to be analyses, press “start” as soon as the last sample has been inserted, to proceed with the analysis.

SHAKING

Once the loading phase has been completed, the instrument will commence the sample shaking phase.
The shaking phase is run by two motors: The translator that turns the plate by 90 degrees and another motor that makes the plate rotate on itself.
During this phase which lasts for 15 minutes, the blood in the test-tubes is shaken in order to make sure that the red blood cells are homogeneously suspended.

REFERENCE READING

When shaking has been completed, the instrument makes a reading of each sample that checks the blood level inside the test-tube.

SEDIMENTATION

After the reference reading, the instrument waits for another 15 minutes for the erythrocytes to settle.

ANALYTICAL READING

The last phase of the cycle is the final reading, that allows the instrument to calculate the ESR values, which are then forwarded to the user, via the preset modes.

N.B. it is possible to abort analysis at any time by pressing the key ESC and then pressing the key OK.

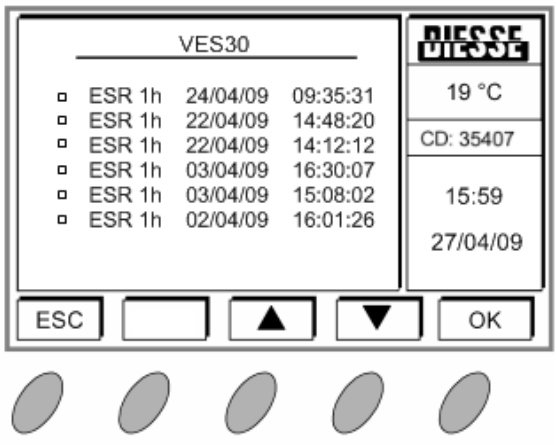
4.7. HOST QUERY

As already stated, the Ves-Matic Cube 30 carries out ESR tests directly on test-tubes used by the blood cell counter in the laboratory.
By activating the host query, it is also possible to choose the samples that must carry out the ESR analysis, during the loading phase.
In fact, when the sample code is read by the instrument, it also carries out a host query and once the answer has been received, it will show up on the screen whether the sample must be analysed or not (details on protocol section 7).

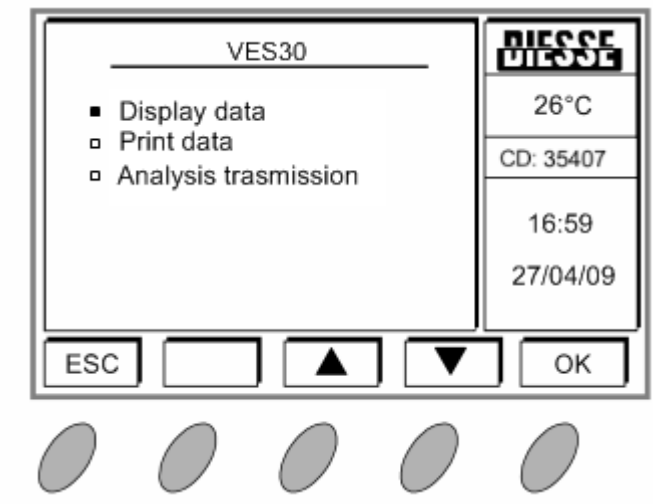
4.8. VISUALISING (AND PRINTING) OF STORED ANALYSES

Procedure:

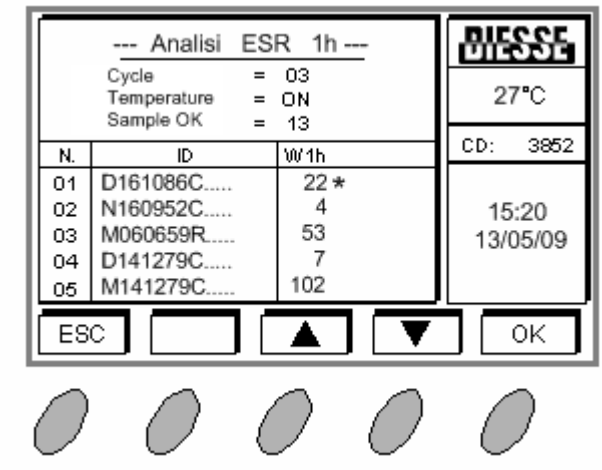
- By pressing the key **Mem**, the following list appears, if the instrument has carried out at least 1 analysis cycle:



- The arrow keys are used to select the test results to be analysed and then the next menu appears once OK has been pressed:



- The operator can now decide whether to show the test results (A) on the screen or whether to print them:
  E.g. of screen display

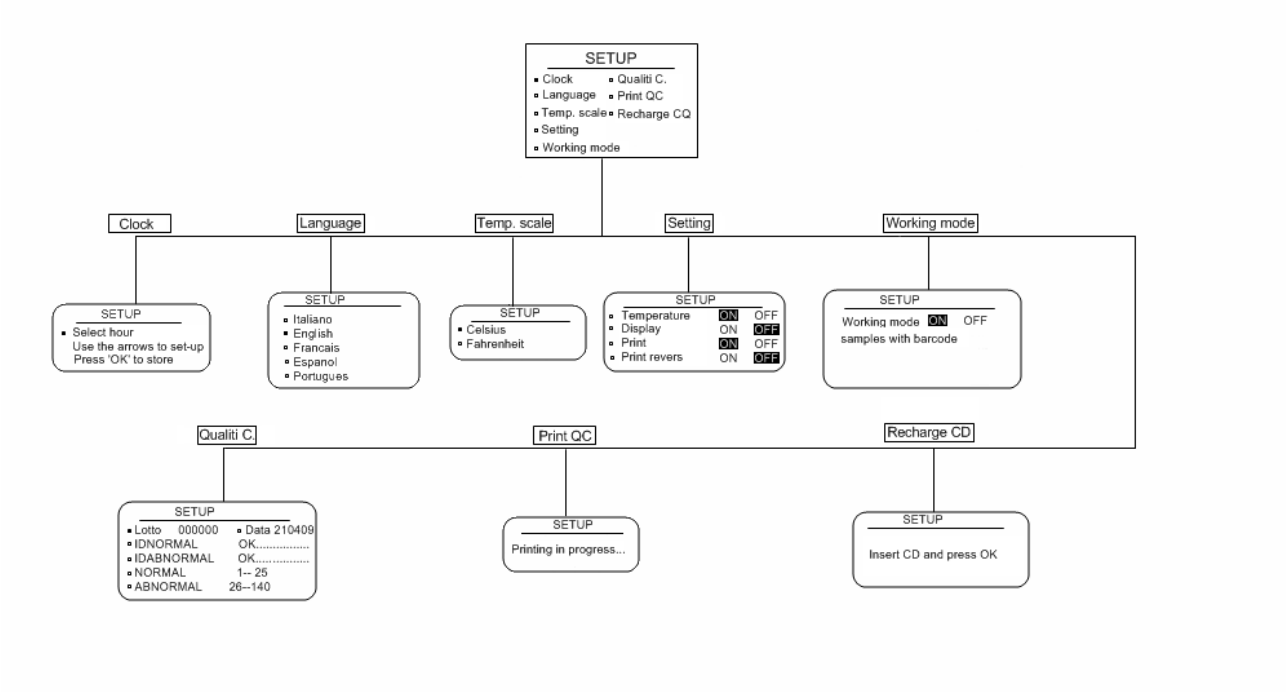


- To return to the previous menu, press the key **ESC**

4.9 INSTRUMENT SETUP

It is possible to access a series of configurations by entering User Setup

.



4.9.1. CLOCK

By entering the clock from the User Setup menu, it is possible to update the time and the date.

After entering the submenu, the following screen will appear, to set the time:
To change the submenu selected, use the arrow keys
By pressing the OK key, confirm the entered value (the confirmation message Memorised! Appears on the display, and then proceed to next item.
(set sequence – hours, minutes, date, month, year)
At the end of the sequence, the programme automatically reappears to the “Setup” menu.

4.9.2. LANGUAGE

Permits the instrument language to be chosen, in fact, the following window appears when we select this command:

To change the language, select the language required (moving up and down using the arrow keys) and then press the key “OK”.

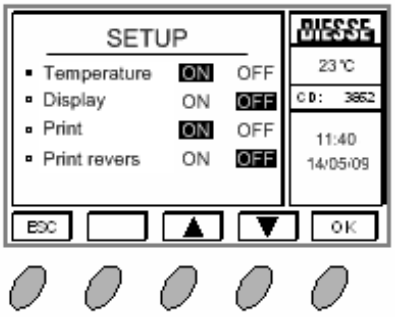
4.9.3 TEMPERATURE SCALE

This setting allows you to change the temperature scale, choosing between degrees Celsius or degrees Fahrenheit.

4.9.4 PARAMETERS

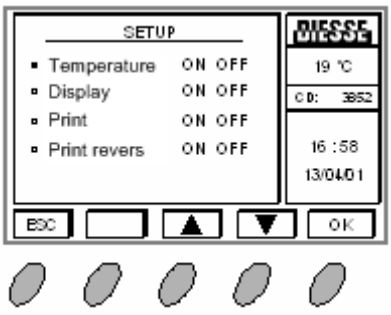
This screen allows you to change some parameters.

Enable/disable the Temperature correction



If the “temperature” parameter is set to ODD, the instrument determines the value of erythrosedimentation rate (ESR) and shows the results at ambient temperature.
However, it can be programmed to show the results at a temperature of 18°C, setting the parameter to **ON**.
We advise the use of this function, especially in laboratories with temperatures above 18°C.
Transformation takes place according to indications from Manley (bibl. ref. 11).
In order to change it, use the arrow keys to be on the temperature item and then press “OK” to change the parameter status.

Enable/disable the Printer and Display settings



If the Display parameter is set to off, results will not appear on the screen.
The Printer parameter allows it to be disabled if results must only be shown on the screen or to the host; due to a temporary lack of paper in the printer or due to malfunction.
The Reverse printing parameter allows the direction of the test’s final report printout to be set.

4.9.5. WORKING MODE

Changing the working mode also changes the instrument loading.
If the working mode is set to ON, the instrument will request the barcode for each sample, and then the introduction of each sample into the instrument (if host connection applies, see paragraph 4.7).
If instead we set the working mode to OFF, the instrument will simply ask to enter the samples inside the instrument and then to press the key OK. This loading mode is much quicker but the only traceability is the position number in the plate.
For this reason, we advise that settings are made according to the samples used
ON – for samples with barcode
OFF – for samples without barcode

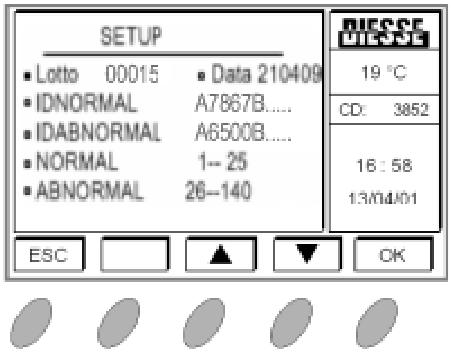
4.9.6. QUALITY CONTROL

With the VES-MATIC cube 30 instrument, it is possible to use the control blood ESR control (code 10430 4x9 MI) that represents a test to monitor Erythrosedimentation rates (ESR).

Please refer to the information leaflet for methods of use and procedures.

Setting the instrument

It is possible to change the control blood parameters from this setting:



- Batch, written on the product information leaflet
- IDNORMAL/IDAMNORMAL, are the codes shown on the control blood sample thanks to which the instrument recognises them
- NORMAL/ABNORMAL, are the ranges of acceptability for that control blood sample (information leaflet)
- Date, is the expiry date for the ESR control (information leaflet 80808080)

To change the values, move up and down the items using the arrow keys. The set value can be changed by scrolling with the arrows and then pressing OK.

4.9.7 QC PRINTING

This function is used to print the settings for control blood

4.9.8 CD RECHARGING

This operation permits recharging of the Check device (see paragraph 5.4)

CHAPTER 5

MAINTENANCE 35

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- 5.6 VERIFICATION OF SAFETY (MICROSWITCHES) AND ACOUSTIC DEVICES 38

5.1. GENERAL RECOMMENDATIONS

The VES-MATIC cube 30 has been designed and produced to require minimum maintenance.

For any type of maintenance work:
Disconnect instrument from power supply
- Use the personal protection features, foreseen during functioning
-Do not remove casing and do not remove safety devices

In caso di fuoriuscita di sangue, durante il ciclo di lavoro, per pulire le superfici esterne dello strumento, utilizzare i dispositivi previsti per la sicurezza personale.

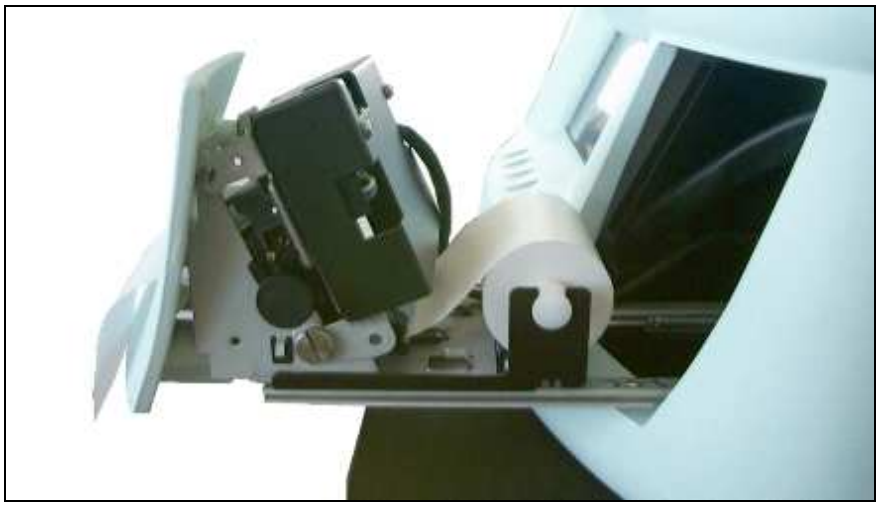
5.2. EXTERNAL CLEANING OF THE INSTRUMENT

External cleaning is required for safety reasons. Use a mild, non-aggressive detergent.
Contact an authorised Assistance Centre for internal cleaning.

5.3. REPLACEMENT OF PRINTER PAPER

Procedure:

1. Disconnect instrument from power supply.
2. Press the printer hatch inwards, and a click mechanism will open it.
3. Remove the paper pin.
4. Substitute the old paper roll with a new one.
5. Lift up the printer head, using the side lever.



6. Insert the end of the paper strip in the opening of the paper guide, taking care to level it precisely with a pair of scissors and respecting the paper rotation direction

7. Turn on the power supply.
8. Push the paper as far as possible, until it begins to load automatically.
9. Lower the print head lever.
10. The paper enters until it comes out of the front of the printer; if the paper does not come out, press the key S2 (top left on the control board).
11. Pull the paper outwards so that it is cut.
12. Rip off the paper jutting out of the front of the printer.

Close the hatch.

5.4. SUBSTITUTION OF THE CHECK DEVICE

The “check device” is an electronic device that allows the instrument to have a defined number of executable tests available. For every result the check device will automatically undergo a decrease of the number of available tests. Once the tests have been loaded, it is necessary to recharge the instrument using the special “Check Device Transponder RF” (see figure). The test-tube looks like a normal vacutainer test-tube and can be used to load any instrument into the Ves-Matic Cube line.

The Ves-Matic Cube 30 is supplied as already controlled and ready to carry out the first ESR tests without any recharging.

To carry out check device recharging, it is necessary to follow the simple procedure described below with the instrument turned on but when no analysis cycle is running:

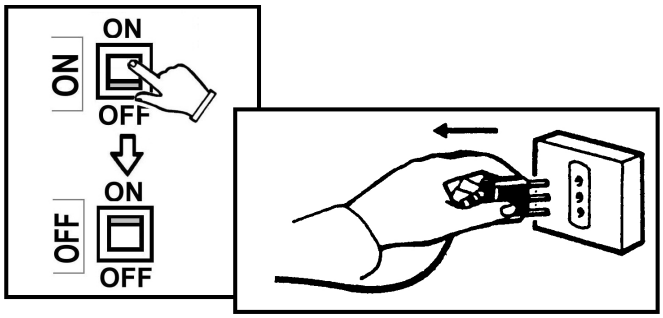
1. Open the Ves-Matic Cube 30 lid.
2. Enter setup/user/Recharge_Cd from the menu
3. The instrument will ask you to introduce the “Check Device Transponder RF” into the specific housing (see figure).
4. Press OK
5. At this point, the instrument will show a message stating that recharging has been completed and the test counter will increase.

Replace the Check-Device when it is not completely worn out, when there are at least about sixty tests that can still be carried out.

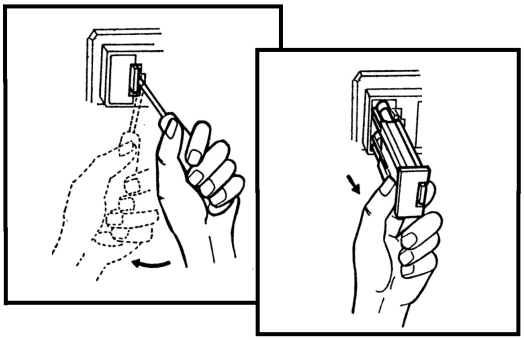
5.5. REPLACEMENT OF THE FUSES

If it necessary to replace fuses, **proceed as follows**:

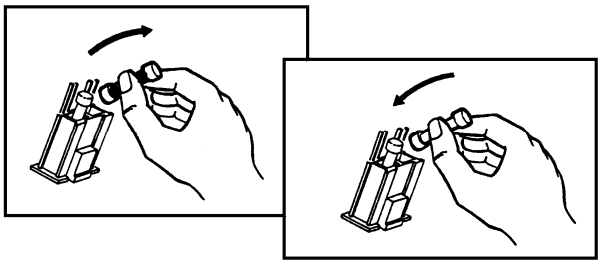
1. Turn off the instrument and disconnect it from the power supply



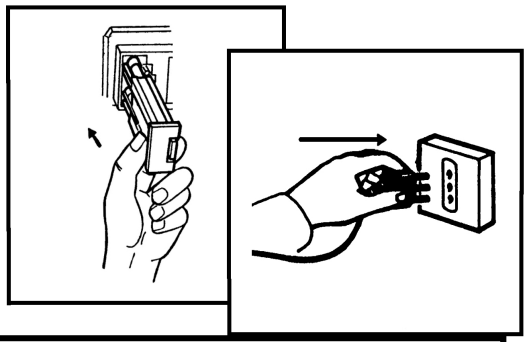
2. Remove the fuse box using a straight screwdriver



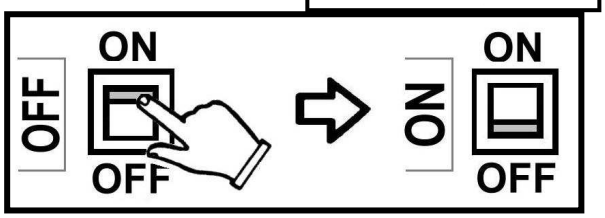
3. Replace the damaged fuses with new ones supplied with the instrument.



4. Return fuse box and reconnect instrument to power supply.



5. Turn on the power supply.



If the fuses blow again when the machine is turned on, contact Technical Assistance.

5.6. VERIFICATION OF SAFETY (MICROSWITCHES) AND ACOUSTIC DEVICES

To check that safety devices work correctly, carry out the following procedure.

1. Open the hatch when the instrument is turned off
2. Turn on the instrument. At this point, the instrument will provide an *acoustic signal* if the instrument works correctly.
3. Close the hatch and check that it is blocked in order to carry out reset.

At this point, if the instrument works correctly, the two conditions (acoustic signal and blocking) must be checked. If they do not work, contact technical assistance.

CHAPTER 6

AUTO-DIAGNOSTICS 40

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6.1. AUTO-DIAGNOSTICS

In addition to carrying out command and control operations for peripherals, the microprocessor constantly controls the most important parts of the instrument.
When a fault occurs, the current running cycle is automatically interrupted and an acoustic signal is sent. At the same time, the type of fault and problem appears on the Display screen.
The messages are as follows:

MESSAGE AND FAULT	CAUSE AND SOLUTION
ERROR READING	
This occurs if the movement of the reading unit is not completed within the set time limit.	In addition to possible electrical faults, there may be mechanical blocks that must be reserved. In the former hypothesis, technical intervention is necessary. Check that the test-tubes are inserted correctly in the plates.
ERROR PLATE	
If the test-tube holder plate does not make a full rotation in the preset time.	In addition to possible electrical faults, there may be mechanical blocks that must be reserved. In the former hypothesis, technical intervention is necessary.
ERROR TRASLATOR	
If the test-tube holder plate does not make a full translation in the preset time.	In addition to possible electrical faults, there may be mechanical blocks that must be reserved. In the former hypothesis, technical intervention is necessary.
CHECK DEVICE EXHAUSTED	
This occurs when the Check Device is exhausted.	Insert a new Check Device. If the error continues, technical intervention is required.
ERROR PRINTER	
This occurs when the printer has a problem.	Technical intervention is required.

SAMPLE LOW This occurs during the printing phase when the sample level is too low.	Fill the test-tube correctly with the same blood sample.
SAMPLE HIGH This occurs during the printing phase when the sample level is too high.	Check whether there is too much blood in the test-tube and if so, reduce the content in the test-tube, or check that the labels applied to the sample do not exceed the limits (see paragraph 4.2.).
ANALYSIS ABORTED This is printed when the STOP button is pressed during the work cycle.	

After any ERROR warning, the entire operation must be repeated at least once to check that the error is due to external causes, such as, interruption or temporary alteration of power voltage.
Turn off the instrument and wait a few seconds; turn on the instrument again and start up the cycle in the prescribed mode.

CHAPTER 7

CONNECTION TO THE HOST COMPUTER:..... 43

Bi-directional connections to the Host (common to all Ves Cubes) are commented below. For information regarding mono-directional connections, see Ves-Matic instrument manuals with dedicated test-tubes or contact Diesse Diagnostica Senese S.p.a..

Serial Protocol for communication with the Host Computer

The cables used for external connections **must not exceed 3 metres in length**.

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7.1. FOREWORD: TECHNICAL INFORMATION

- The electric levels of the signals are the RS232C standard type.
- The transmission speed is 9600bit/s, the data format is 8 bit of data, 1 stop bit and no parity bit.
- The DB9 Female connector “RS232C” on the Ves-Matic Cube back panel shows the following pin-out:

PIN	SIGNAL
2	Rx data from Host
3	Tx data to Host
5	GND

The type of protocol used sometimes enters codes (e.g. rack and rack position) that are set to default values for the cube 30 but which are essential for aligning the protocol for the entire Ves-Matic Cube line, thus allowing two instrument with the same protocol to be connected.

7.2. FOREWORD: HEX-ASCII REPRESENTATION

In the protocol described below many of the parameters and data are represented in Hexadecimal ASCII (HEX-ASCII) format, in other words:
a byte with a value of 0x7A is represented by two ASCII characters: ‘7’ (0x37) and ‘A’ (0x41), the first represents the most significant nibble and the second, the least significant.

Examples:

Original Byte	**HEX-ASCII Representation**	
Hexadecimal value	H character	L character
0x45	‘4’ (0x34)	‘5’ (0x35)
0xC8	‘C’ (0x43)	‘8’ (0x38)
0x6F	‘6’ (0x36)	‘F’ (0x46)
0x10	‘1’ (0x31)	‘0’ (0x30)

As can be noted this type of representation means that two ASCII characters are necessary for the representation of the value of one byte.

7.3. GENERAL NOTES: RESPONSE DELAYS

To allow the machine time to activate the reception mode it is necessary to enter a delay of 1 second on the reply.

7.4. REQUEST FOR TEST-TUBES TO BE PROCESSED MESSAGE: COMMAND 0X50

This message is sent by the Ves-Matic Cube towards the host computer. The message contains the test tube barcode. The host computer must reply to this message with a similar message containing the barcode, among the ones received from the Ves-matic Cube 80, for the samples that require ESR testing. (i.e. codes that have already been accepted by the host) and in the case of codes that have not yet been accepted by the host (thus unknown).
The management of the samples to executed because they have been accepted on the host and that of the samples to be executed although 'unknown' to the host, is based on an attribute (the terminator of the bar code) contained in the host's reply message (see 7.2.5)

Example 1 (WITHOUT management of 'unknown' codes)
The Ves-Matic Cube sends 10 barcodes to the host. The host sends back only 4 of the 10 codes received, i.e. only the ones that must be analysed by the Ves-Matic Cube itself (the other 6 samples are not processed by the instrument).

Example 2 (WITH management of 'unknown' codes)
The Ves-Matic Cube sends 10 barcodes to the host, the host sends back 4 codes with an ESR attribution to be carried out + 2 codes with the attribution "code unknown". The instrument will execute the 6 samples, at the end of the analysis it will send the results of the 4 codes with ESR to execute, while the other 2 'unknown' codes will stay in the pending database.
Actually, the Ves-Matic Cube 30 sends one code at a time to the host, but it is useful to theorise that 10 sample codes can be sent, in order to be able to use the same connection for any Ves-cube model.

Request: Ves-Matic Cube sends the following frame

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	**H-LEN**	**L-LEN**	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x30)	**Data-1**	**...**	**Data-n**	ETX (0x0D)	**H-CHK**	**L-CHK**

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value 'F' (0x46) / 'F' (0x46). This is the effective number of bytes contained in the **Data** field. In fact, the maximum number of bytes accepted in the DATA field is 255.

Data-1 .. Data-n: Data Field. The data field for the message code consists of the following:

H-NUM / L-NUM (2 bytes HEX-ASCII)	**BarCode-1** (ASCII String max 15 characters)	**Terminator** For the barcode -1 string (0x10)	**BarCode-2** (ASCII String max 15 characters)	**Term.** For the barcode - 2 string (0x10)	… ..	**BarCode-n** (ASCII String max 15 characters)	**Term.** of the Barcode-n string (0x10)

H-NUM / L-NUM: Number of bar codes contained in the message, represented by HEX-ASCII.

BARCODE-n: ASCII string with variable length, maximum of 15 characters allowed. It is the barcode that is read by the Ves-Matic Cube Barcode Reader.

Terminator: Each string of the barcode is terminated with the byte 0x10. This is because the length of this string is variable.
The number of bar codes contained in the data field is limited by the fact that the data field itself can contain a maximum of 255 bytes, in any case the bar codes are never truncated, but always complete with terminator.

7.4.1. H-CHK / L-CHK:
CheckSum of the message, represented in HEX-ASCII. The Checksum is calculated by carrying out the OR-exclusive of all the bytes sent from STX to ETX inclusive. The resulting hexadecimal value is then converted into HEX-ASCII and the two characters that represent it are sent.

ATTENTION: for debugging purposes it is possible to disable the checksum control, replacing the H-COM bytes with the value of 0x44 instead of 0x35. In this case the two bytes of the checksum are still sent but their value will be insignificant. The Host computer must also manage any possible cases in which the checksum is disabled.

Reply from the Host Computer
Upon receiving the message, the Host computer has to first send an ACK message to acknowledge correct receipt and interpretation of the message; meaning that all the fields have the correct values and the checksum is correct, or a NACK message to indicate that the message contains one or more errors: inexact checksum, incorrect length of the data field, etc…

ACK message

ACK (0x06)	H-ADD (0x30)	L-ADD (0x31)	ETX (0x0D)

Timeout on ACK Message: 2 Sec.

NACK message

NACK (0x15)	H-ADD (0x30)	L-ADD (0x31)	**H-ERR**	**L-ERR**	ETX (0x0D)

where: **H-ERR / L-ERR** are the HEX-ASCII representation of the error code defined according to the following table:

Error code	**Value of: H-ERR**	**L-ERR Value**	**Meaning**
0x00	0x30	0x30	General Error
0x04	0x30	0x34	Checksum Error
0x05	0x30	0x35	Field value Error H-LEN / L-LEN
0x06	0x30	0x36	Data field Length Error

Timeout on NACK Message: 2 Sec.

7.5. RESPONSE MESSAGE WITH COMMAND DATA

After sending the ACK message, the host computer must send the actual response to the message 0x50. This response will be identical to the message sent by the Ves-Matic Cube 30 (see paragraph 7.4.1) with the only different that the barcodes sent will only be the ones that must be processed by the Ves-Matic Cube and with the further difference of the terminator 0x11 for the "unknown codes" (i.e. not yet accepted on the host computer and therefore to be processed anyway). Therefore the **H-LEN/L-LEN and H-NUM/L-NUM** fields may be different.
If none of the barcodes must be processed, the **Data** field will only contain the H-NUM / L-NUM (0x30 / 0x30 value) field and H-LEN /L-LEN will be equal to 0x30 / 0x32.

The data field for the message code consists of the following:

H-NUM / L-NUM (2 bytes HEX-ASCII**)**	**BarCode-1** (ASCII String max 15 characters)	**Terminator** For the barcode -1 string (0x10/0x11)	**BarCode-2** (ASCII string max 15 characters)	**Terminator** of the Barcode-2 string (0x10/0x11)	… ..	**BarCode-n** (ASCII string max 15 characters)	**Terminator** of the Barcode-n string (0x10/0x11)

H-NUM / L-NUM: Number of bar codes contained in the message, represented by HEX-ASCII

BARCODE-n: ASCII string with variable length, maximum of 15 characters allowed. It is the barcode that is read by the Ves-Matic Cube Barcode Reader.

Terminator: Every string of the bar code is terminated by a 0x10 byte or a 0x11 byte (for "unknown" codes). This allows the management of the variable length of the codes as well the management of "unknown codes".
The number of bar codes contained in the data field is limited by the fact that the data field itself can contain a maximum of 255 bytes, in any case the bar codes are never truncated, but always complete with terminator.
If the barcode string ends with the byte 0x10, it means that the sample must be processed by the Ves-Matic Cube. At the end of the test, the result will be printed out and stored in the historical database.
If the barcode string ends with the byte 0x11, it means that the sample code is unknown; in this case, the Ves-Matic Cube will process the sample but the result will not be printed at the end of the test, but will be stored in the Pending Database.

Timeout on Message with Data: 5 Seconds.

7.5.1 Error on Reply Message with Data

If the Ves-Matic Cube detects an error in the reception of this message, it will repeat the transaction from the beginning, resending the request message as set out in paragraph 7.4.1.

7.6. RESULT SENDING MESSAGE: COMMAND 0X51

This message is sent by the Ves-Matic Cube towards the host computer. The message contains the results of the analysis performed on one or more samples. The host computer must only reply to this message with an ACK or NACK type message to notify the successful receipt of the results or the presence of errors in the message.
N.B.: the samples that were analyzed by the instrument with the attribute "unknown code" are not sent automatically at the end of the analysis process but can only be sent manually by the operator by means of the command "Send to host" from the management menu of the pending database.
Control: Ves-Matic Cube sends the following frame

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	**H-LEN**	**L-LEN**	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x31)	**Data-1**	**...**	**Data-n**	ETX (0x0D)	**H-CHK**	**L-CHK**

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value 'F' (0x46) / 'F' (0x46). This is the effective number of bytes contained in the data field**.** In fact, the maximum number of bytes accepted in the DATA field is 255.

Data-1 .. Data-n: Data Field. The data field for the message code 0x51 is as follows:

H-PRO / L-PRO (2 bytes HEX-ASCII)	Test Tube-1 Record	……	Test Tube-n Record

H-PRO / L-PRO: Number of Test Tube records contained in the message, represented in HEX-ASCII.
The Test Tube Record number contained in the data field is limited by the fact that the data field itself is able to contain up to a maximum of 255 bytes, in any case the test tube records are never truncated.

Test-tube record:

Barcode (ASCII String max 15 characters)	**Terminator** of the string Barcode (0x10)	**ANALYSIS DATE** ASCII String 6 characters	**ANALYSIS TIME** ASCII String 4 characters	**ESR** ASCII String 4 characters	**H-FLAGS**	**L-FLAGS**	**RACK ID** ASCII String 4 characters	**POSITION** ASCII ASCII String 2 characters

BARCODE: ASCII string with variable length, maximum of 15 characters allowed. It is the barcode that is read by the Ves-Matic Cube Barcode Reader.

Terminator: The barcodes string terminates with the 0x10 byte. This is because the length of this string is variable.

DATA ANALYSIS: String of 6 characters without **"DDMMYY"** terminator, where:
"DD" = day of the month, from "01" to "31" ASCII.
"MM" = Month of the year, from "01" to "12" ASCII.
"YY" = Year of the century, from "00" to "99" ASCII.

ANALYSIS TIME : String of 4 characters without **"hhmm"** terminator, where:
"hh" = hour of the day, from "00" to "23" ASCII.
"mm" = Minutes, from "00" to "59" ASCII.

ESR: Value of the ESR measured, ASCII string without terminator: from " 0" (3 Spaces + '0') transmitted in the case of an error, to "140" (1 Space + "140"). If the result is higher than 140 the string will be ">140".

EXAMPLES: See following table:

ESR value	String sent	Bytes of the string
1	“ 1”	0x20, 0x20, 0x20, 0x31
100	“ 100”	0x20, 0x31, 0x30, 0x30
>140	“>140”	0x3E, 0x31, 0x34, 0x30

N.B.: If traceability has been activated inside the sample holder rack, the ESR result may be 0 (with no error flag). In this case, it means that the sample in question has not been analysed, as requested by the host.

H-FLAGS / **L-FLAGS**: 8-bit Bitmap of the sample errors, represented in HEX-ASCII. The following table illustrates the errors:

Bit	Error	Description
0	Sample High	Sample tube overfilled
1	Sample Low	Sample tube underfilled (<1.5 ml)
2	Sample Absent	Test Tube Empty
3	Reading error	General reading error
4	QC PASS	Reserved for samples with control blood
5	QC FAIL	Reserved for samples with control blood
6-7	-	Reserved

EXAMPLES:

- In the case of a “Sample High” error the Bit 0 (least significant) will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x01 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x31.
- In the case of a “Sample Absent” error the Bit 2 will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x04 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x34.

Management of UNCERTAIN RESULT

If a Test Tube record is sent with an ESR value equal to 0 and with an error flag active (Bit 3 set to 1), the result (ESR=0) must be interpreted by the Host as ‘Sample reading error’.

If a Test Tube record is sent with an ESR value different from 0 and with an error flag active (Bit 3 set to 1), the result (ESR different from 0) must be interpreted by the Host as an ‘Uncertain Result’, in the report the result is printed and indicated with an asterisk.

RACK ID: A string of 4 characters without terminator identifies the sample holder rack in which the sample has been repositioned.

POSITION: A string of 2 characters without terminator identifies the co-ordinates of the position in which the sample has been repositioned in the sample holder rack.

H-CHK / L-CHK: CheckSum of the message, represented in HEX-ASCII. The Checksum is calculated by carrying out the OR-exclusive of all the bytes sent from STX to ETX inclusive. The resulting hexadecimal value is then converted into HEX-ASCII and the two characters that represent it are sent.

For debugging purposes, it is possible to disable the checksum control, replacing the byte H-COM with the value 0x44 instead of 0x35. In this case the two bytes of the checksum are still sent but their value will be insignificant. The Host computer must also manage any possible cases in which the checksum is disabled.

Reply from the Host Computer

Upon receiving a message, the Host computer must send an ACK message to acknowledge correct receipt and interpretation of the message, meaning that all the fields have the correct values and the checksum is correct; or a NACK message to indicate that the message contains one of more errors: inexact checksum, incorrect length of the data field, etc (see paragraph 7.4.2).

7.7. QC (QUALITY CONTROL) SAMPLE DATA SENDING MESSAGE: COMMAND 0X52

This message is sent by the Ves-Matic Cube towards the host computer. The message contains the results of the analysis performed on one or more samples. The host computer must only reply to this message with an ACK or NACK type message to notify the successful receipt of the results or the presence of errors in the message.

Control: Ves-Matic Cube sends the following frame

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	**H-LEN**	**L-LEN**	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x32)	**Data-1**	**...**	**Data-n**	ETX (0x0D)	**H-CHK**	**L-CHK**

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value ‘F’ (0x46) / ‘F’ (0x46). This is the effective number of bytes contained in the data field**.** In fact, the maximum number of bytes accepted in the DATA field is 255.

Data-1 .. Data-n: Data Field. The data field for the message code 0x52 is composed as follows:

QC Data	**QC Test Tube Record:**

QC Data

Batch No. (ASCII string 6 characters)	**EXPIRY DATE** ASCII String 6 characters	**H-VALMIN**	**L-VALMIN**	**H-VALMAX**	**L-VALMAX**

BATCH No.: ASCII string of 6 characters. Identifies the production batch of the control blood.

EXPIRY DATE: String of 6 characters without **"DDMMYY"** terminator, where:
"DD" = day of the month, from "01" to "31" ASCII.
"MM" = Month of the year, from "01" to "12" ASCII.
"YY" = Year of the century, from "00" to "99" ASCII.

H-VALMIN / L-VALMIN: The minimum value of the acceptable range for the control blood, represented in HEX-ASCII.

H-VALMAX / L-VALMAX: The maximum value of the acceptable range for the control blood, represented in HEX-ASCII.

QC Test Tube Record:

Barcode (ASCII String max 15 characters)	**Terminator** of the string Barcode (0x10)	**ANALYSIS DATE** ASCII String 6 characters	**ANALYSIS TIME** ASCII String 4 characters	**ESR** ASCII String 4 characters	**H-FLAGS**	**L-FLAGS**	**RACK ID** ASCII String 4 characters	**POSITION** ASCII ASCII String 2 characters

BARCODE: ASCII string with variable length, maximum of 15 characters allowed. It is the barcode that is read by the Ves-Matic Cube Barcode Reader.

Terminator: The barcodes string terminates with the 0x10 byte. This is because the length of this string is variable.

DATA ANALYSIS: String of 6 characters without **"DDMMYY"** terminator, where:
"DD" = day of the month, from "01" to "31" ASCII.
"MM" = Month of the year, from "01" to "12" ASCII.
"YY" = Year of the century, from "00" to "99" ASCII.

ANALYSIS TIME : String of 4 characters without **"hhmm"** terminator, where:
"hh" = hour of the day, from "00" to "23" ASCII.
"mm" = Minutes, from "00" to "59" ASCII.

ESR: Value of the ESR measured on the QC sample, ASCII string without terminator:
from " 0" (3 Spaces + '0') transmitted in the case of an error, to "140" (1 Space + "140"). If the result is higher than 140 the string will be ">140".

EXAMPLES: See following table:

ESR value	String sent	Bytes of the string
1	“ 1”	0x20, 0x20, 0x20, 0x31
100	“ 100”	0x20, 0x31, 0x30, 0x30
>140	“>140”	0x3E, 0x31, 0x34, 0x30

H-FLAGS / L-FLAGS: 8-bit Bitmap of the sample errors, represented in HEX-ASCII. The following table illustrates the errors:

Bit	Error	Description
0	Sample High	Sample tube overfilled
1	Sample Low	Sample tube underfilled (<1.5 ml)
2	Sample Absent	Test Tube Empty
3	Abnormal	Error in acquisition of height
4	QC PASS	The ESR of the QC measured is within the acceptability range
5	QC FAIL	The ESR of the QC measured is outside the acceptability range
6-7	-	Reserved

EXAMPLES:

- In the case of a “Sample High” error the Bit 0 (least significant) will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x01 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x31.
- In the case of a “QC Fail” error the Bit 5 will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x20 hexadecimal value and its HEX-ASCII representation will be 0x32 / 0x30.

RACK ID: A string of 4 characters without terminator identifies the sample holder rack in which the sample has been repositioned.

POSITION: A string of 2 characters without terminator identifies the co-ordinates of the position in which the sample has been repositioned in the sample holder rack.

Reply from the Host Computer

Upon receiving a message, the Host computer must send an ACK message to acknowledge correct receipt and interpretation of the message, meaning that all the fields have the correct values and the checksum is correct; or a NACK message to indicate that the message contains one of more errors: inexact checksum, incorrect length of the data field, etc (see paragraph 7.4.1).

7.8. EXAMPLE OF SERIAL PROTOCOL

1. Example for the ESR analysis request on two samples (two barcodes, see paragraph 7.4.1)

ATTENTION: The non-printable characters (<0x20) are represented with their hexadecimal value between brackets [0x..]

Ves-Matic Cube TX:

>00140150020109105 3[0x10]20586743[0x10][0x0D]36

STX	H/L BLK	H/L LEN	H/L ADD	H/L COM	H/L NUM	SAMPLE 1 BAR CODE + TERMINATOR	SAMPLE 2 BAR CODE + TERMINATOR	ETX	H/L CHK
>	00	14	01	50	02	01091053[0x10]	20586743[0x10]	[0x0D]	36

STX : [0x3E] '>'.
H/L BLK : fixed value '00'
H/L LEN: number of characters in the data field (14 hex = 20 characters: 2 per H/L NUM + 9 SAMPLE 1 BARCODE+ TERMINATOR + 9 SAMPLE 2 BARCODE+ TERMINATOR)
H/L ADD : fixed value '01'
H/L COM : command code "for sample code to be processed request ": '50'.
H/L NUM: number of barcode included in this message (02 hex = 2 bar codes)
SAMPLE 1 BAR CODE + TERMINATOR
SAMPLE 2 BAR CODE + TERMINATOR
ETX : character [0x0D]
H/L CHK: "xor" of all characters from STX to ETX included.

2. Example of request for authorisation to Host for two barcodes of two samples and authorisation response for analysis only for the second (see paragraph 7.4.3.)
ATTENTION: The non-printable characters (<0x20) are represented with their hexadecimal value between brackets [0x..]

Request Ves-Matic Cube TX:

>00140150020109105 3[0x10]20586743[0x10][0x0D]36

Host Message TX ack:

[0x06]01[0x0D]

Host Reply TX:

>000B01500120586743[0x10][0x0D]5D

STX	H/L BLK	H/L LEN	H/L ADD	H/L COM	H/L NUM	SAMPLE 2 BAR CODE + TERMINATOR	ETX	H/L CHK
>	00	0B	01	50	01	20586743[0x10]	[0x0D]	5D

STX : [0x3E] '>'.
H/L BLK : fixed value '00'
H/L LEN: number of characters present in the data field (0B hex = 11 characters: 2 for H/L NUM + 9 SAMPLE 2 BARCODE+ TERMINATOR)
H/L ADD :fixed value '01'
H/L COM : command code "for sample code to be processed request ": '50'.
H/L NUM: number of barcodes included in this message (01 hex = 1 bar code)
SAMPLE 2 BAR CODE + TERMINATOR
ETX : character [0x0D]
H/L CHK: "xor" of all characters from STX to ETX included.

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ANNEXES

ANNEX A

EC DECLARATION OF CONFORMITY

In accordance with 98/79/EEC regulation regarding In-Vitro Medical Diagnostics Devices

DIESSE Diagnostica Senese S.p.A.

DIESSE DIAGNOSTICA SENESE S.p.A. with head office in Milan, Via A. Solari 19 sc. 6

certifies

that the design, type of manufacture of the in vitro medical-diagnostics device described hereafter and the version distributed on the market,

conforms

to the

" 98/79/EEC directive relevant to the In Vitro Medical-Diagnostics Devices (IVD)"

through the accomplishment to the Annex III (except section 6) and the essential requirements of Annex I.

This certificate will lose its validity in the event of:
- modifications made to the machine in question without our authorization
- incorrect use of the instrument
- technical interventions performed by unauthorized personnel
- installation of non-original spare parts.

Product:	**Automatic instrument for ESR analysis**
Type:	**VES-MATIC CUBE 30**
Technical data:	**110/120/230 Vac (56–60 Hz)**

conforms

as a whole and in its parts, with the following standards and their amendments:

EN 61010-1 **"Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements ".**

EN 61326-1 **"Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements–Part 1: General requirements"**

And therefore meets the minimum requirements of the following Community directives and their amendments:

Low Voltage Directive (2006/95/EEC)

Electromagnetic Compatibility Directive (89/336/EEC, 93/68/EEC and 2004/108/EEC)

Place, date of issue: Monteriggioni, 01 April 2009

Signature:

Francesco Cocola
General Manager

This is the certified copy of the original document stored in archive of DIESSE Diagnostica Senese SpA.

Issued: Monteriggioni, 20 April 2010

Gabriele Monciatti
R.A. Manager

ANNEX B

WARRANTY CERTIFICATE

Y/N_____

Terms:

1. The warranty will only be acknowledged if the warranty certificate is sent, together with a copy of the transport documents and the installation report, within 15 days of delivery.
2. This produce will not be considered to have material or manufacturing faults if it is adapted, changed or regulated to comply with national or local regulations in force in a country other than the one for which the product was originally designed and made. This warranty shall not cover said adaptations, modifications or adjustments or any attempts at the same, irrespective of whether performed correctly or incorrectly, or any damage deriving from the same.
3. This warranty shall not cover:

   periodic checks, maintenance and repairs or replacement of parts due to normal wear and tear,

   transport costs and risks linked directly or indirectly to the warranty of this product, including the transfer from the assistance centre to the customer's address,

   Damage due to negligence and improper use of the instrument,

   malfunctioning of the instrument due to modifications or repairs carried out thereon by unauthorised third parties.

   damage caused by the assembly of parts or components not approved by the manufacturer.

Copy to be filled in and stored for the period of Warranty, together with the Instruction Manual.

Y/n _____
PURCHASER _____
ADDRESS _____
CITY' _____ STATE _____ ZIP _____
MODEL _____ TYPE _____ REGISTRATION NUMBER _____
DELIVERY NOTE NUMBER _____ DELIVERY NOTE DATE _____
DEALER _____
ADDRESS _____
INSTALLER _____
ADDRESS _____

COPY TO BE FILLED IN AND SENT TO
DIESSE DIAGNOSTICA SENESE Spa.,Via delle Rose 10, 53035 Monteriggioni Siena -Italy

Y/n _____
PURCHASER _____
ADDRESS _____
CITY' _____ STATE _____ ZIP _____
MODEL _____ TYPE _____ REGISTRATION NUMBER _____
DELIVERY NOTE NUMBER _____ DELIVERY NOTE DATE _____
DEALER _____
ADDRESS _____
INSTALLER _____
ADDRESS

ANNEX C

REQUEST FOR ASSISTANCE

AUTHORISED ASSISTANCE CENTRES TO BE CONTACTED:

Information to specify in written requests:

Instrument data:

MODEL _____

TYPE _____

DATE OF PURCHASE _____

y/n (warranty certificate) _____

2 Customer data:

NAME _____

ADDRESS _____

CITY' _____ STATE _____ ZIP _____

3 Dealer's data:

NAME _____

ADDRESS _____

FAULT OR BREAKDOWN FOUND ON INSTRUMENT:

_____

_____

_____

ANNEX D

Spare Parts Request Form

INSTRUMENT _____ MODEL _____ SN# 200 [ ]-[ ][ ]-[ ][ ][ ][ ]

CUSTOMER/COMPANY _____

ADDRESS _____

CITY' _____ ZIP _____ STATE _____

T.D. n° [ ] of [ ]

Remarks:

Code	Description	Pack.	Requested quantity

Date _____ . Signature _____.

Fill out and send a legible copy of the following to:

DIESSE ASSISTANCE SERVICE	**CUSTOMER CARE** Via del Pozzo 5, 53035 Monteriggioni (SI), Italy Tel. ++39 0577 319556 Fax. ++39 0577 319020 e-mail: customercare@diesse.it

ANNEX E

METHOD MANUAL ACCORDING TO WESTERGREN'S TECHNIQUE FOR DETERMINING THE ESR.

In order to measure the ESR according to Westergren's technique follow the recommendations of the International Committee for Standardisation in Haematology (ICSH) (bibliog. ref.12/13), outlined below.

Materials

Blood collected no later than three hours previously on EDTA-K2 (1.5 ±0.25 mg per mL of blood) or su EDTA-K3 (1.7±0.3 mg per mL of blood) The haematocritical value must be between 30 and 36% (PCV - packed cell volume 0.33 ± 0.03).

Anti-coagulant/diluting solution comprising Trisodium Citrate Dihydrate 1009 mmol/L (3.28 g dissolved in 100 ml of distilled water).

- Glass sedimentation test tubes with the following dimensions: total length 300±1.5 mm, internal diameter 2.55±0.15 mm with a uniformity of ±0.05 mm, graded scale 200±0.35 mm long, subdivided into 10 mm steps or less with a maximum error tolerance between two consecutive divisions of 0.2 mm; the test tubes must be cleaned, dried and free of any residual traces of detergent before use.
- Supporting rack for holding the test tubes in a perfectly vertical position (±1°) and structured so as to be completely stable to prevent any spillage of the blood from the test tubes.

Procedure

Dilute the blood collected in EDTA, after careful though not too vigorous shaking, with the citrate 109 mmol/L in a proportion of 4+1 (for example, 2 mL of blood + 0.5 mL of citrate); mix the blood with the citrate carefully for a long time, but not vigorously, and draw up into Westergren test tubes; place the test tubes in the supporting rack making sure not to expose to direct sunlight, vibrations or impact; after exactly 60 minutes read the distance in mm between the lower meniscus of the plasma and the level of the column of sedimented erythrocytes.